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Proposed Maximum Residue Limit PMRL2016-49

Spinetoram

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various commodities to the product label of Delegate™ Insecticide, containing technical grade spinetoram, is acceptable. The specific uses approved in Canada are detailed on the label of Delegate™ Insecticide, *Pest Control Products Act* Registration Number 28778.

The evaluation of this spinetoram application indicated that the end-use product has value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for spinetoram is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to replace or be added to the MRLs already established for spinetoram, are as follows.

Table 1 Proposed Maximum Residue Limits for Spinetoram

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Spinetoram	**XDE-175-J:** (2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*, 16a*S*,16b*R*)-2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12, 13,14,16a,16b-hexadecahydro-14-methyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione and **XDE-175-L:** (2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*, 16a*S*,16b*S*)-2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a, 5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1*H*-as-indaceno[3,2-*d*] oxacyclododecin-	8.0	Leafy vegetables (Crop Group 4-13, except head lettuce and leaf lettuce)[a], leaf petioles vegetables (Crop Subgroup 22B)[b]
		2.0	*Brassica* head and stem vegetable group (Crop Group 5-13)[c]
		0.4	Fruiting vegetables (Crop Group 8-09)[d]

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
	7,15-dione including the metabolites **N-demethyl-175-J:** (2*R*,3a*R*,5a*R*, 5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-9-ethyl-14-methyl-13-{[(2*S*,5*S*,6*R*)-6-methyl-5-(methylamino)tetrahydro-2*H*-pyran-2-yl]oxy}-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-d]oxacyclododecin-2-yl 6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranoside and **N-formyl-175-J:** (2*R*,3*S*,6*S*)-6-({(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-d]oxacyclododecin-13-yl}oxy)-2-methyltetrahydro-2*H*-pyran-3-yl(methyl)formamide	0.2	Pome fruits (Crop Group 11-09)[e], stone fruits (Crop Group 12-09)[f]
		0.04	Stalk and stem vegetables (Crop Subgroup 22A)[g]

[1] ppm = parts per million

[a] The MRL of 8.0 is proposed to replace the current established MRL of 7.0 ppm for crop group 4 (except leaf and head lettuce) and include all food commodities in the revised crop group 4-13, except head and leaf lettuce.

[b] The MRL of 8.0 is proposed to replace the current established MRL of 7.0 ppm for celery and include all food commodities in the revised crop subgroup 22B.

[c] The MRL of 2.0 is proposed to replace the current established MRL of 2.0 ppm for crop subgroup 5A and include all food commodities in the revised crop group 5-13.

[d] The MRL of 0.4 is proposed to replace the current established MRL of 0.2 ppm for crop group 8 and include all food commodities in the revised crop group 8-09.

[e] The MRL of 0.2 is proposed to replace the current established MRL of 0.1 ppm for crop group 11 and include all food commodities in the revised crop group 11-09.

[f] The MRL of 0.2 is proposed to replace the current established MRL of 0.2 ppm for crop group 12 and include all food commodities in the revised crop group 12-09.

[g] The MRL of 0.04 is proposed to replace the current established MRL of 0.04 ppm for asparagus and include all food commodities in the revised crop subgroup 22A.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for spinetoram in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food and Feed website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Leafy vegetables (Crop Group 4-13, except head and leaf lettuce)	8.0	8.0 (Crop Group 4)	10 (leaf and head lettuce) 8 (spinach)
Leaf petioles vegetables (Crop Subgroup 22B)	8.0	8.0 (Crop Group 4)	6 (celery)
Brassica head and stem vegetables (Crop Group 5-13)	2.0	2.0 (Crop Subgroup 5A)	0.3 (Crop Group 5)
Fruiting vegetables (Crop Group 8-09)	0.4	0.4 (Crop Group 8)	0.06 (tomato)
Stone Fruits (Crop Group 12-09)	0.2	0.2 (Crop Group 12)	0.3 (peach and nectarine)
Pome fruits (Crop Group 11-09)	0.2	0.2 (Crop Group 11)	0.05 (Crop Group 11)
Stalk and stem vegetables (Crop Subgroup 22A)	0.04	0.04 (asparagus)	None

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spinetoram up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document).

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the MRL Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

No new residue data were submitted for spinetoram in support of the amendment to the Delegate™ Insecticide label. The approved use pattern on the revised crop groups was determined to be within that of the registered label. Therefore, the previously reviewed residue data was reassessed in the framework of the current submission.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for spinetoram was based upon the previously reviewed field trial data. MRLs to cover total residues of spinetoram in/on crops are proposed as shown in Table A1.

Table A1 Summary of Field Trial Data Used to Support Maximum Residue Limits

Commodity	Application Method/ Total Application Rate (g a.i./ha)[1]	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)
Spinach	Foliar / 483-527	1	1.48	6.57
Mustard greens	Foliar / 500	1	<0.05	5.77
Broccoli	Foliar / 500	1	0.12	0.47
Cabbage (with wrapper leaves)	Foliar / 500	1	0.02	1.1
Tomato	Foliar / 494-542	1	0.018	0.123
Bell Peppers	Foliar / 503-524	1	0.022	0.074
Non bell peppers	Foliar / 511-514	1	0.039	0.165
Apples (US)	Foliar / 495-577	7	<0.02	0.089
Apples (CAN)	Foliar / 487-510	7	<0.04	0.069
Pears	Foliar / 273-952	7	<0.02	0.08
Peaches	Foliar / 496-521	14	<0.02	0.061
Cherry	Foliar / 489-511	7	<0.02	0.135
Plum	Foliar / 501-518	7	<0.02	<0.02
Celery (untrimmed)	Foliar / 483-527	1	0.397	1.74

[1] g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover total residues of spinetoram. Residues of spinetoram in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.